REMARKS

The Non-Final Office Action mailed April 2, 2009, has been received and reviewed. Prior to the present communication, claims 1-73 were pending in the subject application. All claims stand rejected under § 103(a) and § 112, while claims 1-56 stand rejected under § 101. In response, each of claims 1, 2, 14-17, 21, 22, 25-29, 31, 33-35, 38, 42-44, 48, 49, 51, 52, 57-70, and 73 has been amended herein, while claims 9, 18, 47, 56, 71, and 72 have been canceled and no claims have been added. As such, claims 1-8, 10-17, 19-46, 48-55, 57-70, and 73 remain pending. It is submitted that no new matter has been added by way of the present amendments. Reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Support for Claim Amendments

Independent claim 1 has been amended herein to recite a clarification of the process of determining a list of possible medications to which the patient may be subjected to during a his/her medical procedure(s). In particular, this newly added clarification involves the following steps: "receiving a selection of the person [patient] from a list of patients displayed at a user interface window," where "the list of patients is extracted from patient-procedure entries stored in a unified healthcare network," and where "the patient-procedure entries associate the person with a medical procedure;" "utilizing the medical procedure associated with the selected person to interact with one or more pre-built medication-procedure tables;" and, based on the interaction, "accessing a list of possible medications, and dosages thereof, that are to be administered to the person for the medical procedure." Support for these claim amendments may be found in the Specification, for example, at paragraphs [0028] – [0033], and at FIG. 7, reference numerals 200, 202, and 204.

Further, independent claim 1 is amended to expand upon the process of "outputting a response relating to each match." Accordingly, the process is expanded to recite that "the response indicates a specific medication involved in the match, a category of the specific medication, a type of match, and a severity of an associated atypical clinical event," and that "the type of match is comprises at least one of drug-drug, drug-allergy, or drug-food." Support for this amendment may be found in the Specification, for example, at paragraphs [0037] – [0039], and [0041], and at FIGS. 4-6.

Independent claims 17, 29, 35, 48, 57, and 73 are amended herein to recite a description of comparing a medication list against both an electronic medical record (EMR), and information of the EMR passed through an association table. First, the process of comparing the medication list against the EMR includes the following steps: (a) comparing "the medication list to information in the person's electronic medical record (EMR)," and determining whether "at least one match exists between any of the medications included in the list and the EMR information," where "the match indicates the potential of *drug-allergy reactions* occurring upon the associated medication being administered to the person" (emphasis added). Support for this amendment may be found in the Specification, for example, at paragraphs [0033] – [0034], and [0037], and at FIGS. 2 and 7.

Second, the process of comparing the medication list against the EMR includes the following steps: (a) comparing "the medication list to the information in the person's electronic medical record (EMR) *upon being passed through an association table*," where "the association table includes information regarding adverse affects caused by medications interacting with each other and caused by a medication and a food interacting with each other;" and (b) determining whether "at least one *match exists between any of the medications included in the list and the EMR information passed through the association table*," where "*the match*

indicates the potential of drug-drug or food-drug reactions occurring upon the associated medication being administered to the person" (emphasis added). Support for this amendment may be found in the Specification, for example, at paragraphs [0034] – [0036], and [0037], and at FIGS. 2 and 7.

In general, amendments to the claimed subject matter are not "new matter" within meaning of 35 U.S.C. § 132 or Rule 118 of Patent Office Rules of Practice, unless they disclose an invention, process, or apparatus not theretofore described. Further, if later-submitted material simply clarifies or completes prior disclosure, it cannot be treated as "new matter."[1] By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, "a patent application *necessarily discloses* that function, theory or advantage, even though it says nothing explicit concerning it" (emphasis added).[2] The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.[3] Accordingly, because these amendments are explicitly discussed, and/or inherent to, the procedure for preemptively determining whether an atypical clinical event will occur upon administering a medication, as memorialized in the Detailed Description, the newly recited subject matter is encompassed by the scope of the Specification and does not constitute new matter.

Rejections based on 35 U.S.C. § 112

Claims 1-73 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, independent claims 1, 17, 29, 35, 48, 57, and 73

[1] *Triax Co. v Hartman Metal Fabricators, Inc.*, 479 F2d 951 (1973, CA2 NY); cert. denied, 94 S. Ct. 843 (1973).

[2] *See* MPEP § 2163.07; *In re Reynolds*, 443 F.2d 384 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376 (CCPA 1973).

stand rejected for reciting "if the associated medication were to be administered to the person" in lines 9-10. The Office suggests this recitation is indefinite because it is unclear what would happen if the medication were not administered.

In response, the rejected claims are amended to recite "upon the associated medication being administered to the person." The amendment modifies the claim language into a positive action that is carried out when implementing the invention. Thus, it is no longer indefinite as whether the medication will be administered. As such, the independent claims 1, 17, 29, 35, 48, 57, and 73 are considered to be in condition for allowance, and such favorable action is respectfully requested.

Further, independent claims 1, 17, 29, 57, and 73 stand rejected for reciting "if there is a match" in line 9. The Office suggests this recitation is indefinite because it is unclear what would happen if there was not match.

In response, the rejected claims are amended to recite "when a match is determined to exist." The amendment modifies the claim language into a positive action that is carried out when implementing the invention. Thus, it is no longer indefinite as whether a match will occur. As such, the independent claims 1, 17, 29, 57, and 73 are considered to be in condition for allowance, and such favorable action is respectfully requested.

Rejections based on 35 U.S.C. § 101

Claims 1-56 were rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. In particular, the Office indicates that claims 1-34 are directed to a method that does not conform with the "machine or transformation" test derived from the recent Federal Circuit decision in In re Bilski et al. That is, the Office believes that the

[3] *See id.*

method of independent claims 1, 17, and 29 must (1) be tied to another statutory class, such as a particular apparatus, or (2) transform underlying subject matter, such as an article of manufacture, to a different state or thing.[4]

As amended, each of claims 1, 17, and 29 recites a control server (e.g., computer, machine, or other physical articles for processing) that is employed to "compare the medication list to information in the person's electronic medical record." Accordingly, the use of the specific machine (i.e., control server 22 of FIG. 1) to perform a process imposes meaningful limits on a scope of the claim, and imparts patent-eligibility.[5] Further, the involvement of the specific machine in the claimed process is not merely insignificant extra-solution activity, but serves to support the execution of the method, as discussed above.

As such, it is respectfully submitted that each of amended claims 1, 17, and 29 is directed toward statutory subject matter. Further, each of claims 2-8, 10-16, 19-28, and 30-34 is believed to be in condition for allowance based, in part, upon their dependency from one of independent claims 1, 17, or 29, and such favorable action is respectfully requested.[6]

Further, the Office indicates that claims 35-56 are directed to a system that appears to be software per se without any structural requirements. Applicants have amended independent claims 35 and 48 such that they recite a "computer system comprising a processing device coupled to a computer storage medium, the computer storage medium having stored thereon a plurality of program components executable by the processing device." Applicants respectfully submit that claims 35 and 48, as amended, are not directed to software per se.

Although claims 35 and 48 include program components, these claims are directed to a machine having the program components embodied on a computer storage medium.

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[4] *Ex parte Bilski*, No. 2002-2257, 2006 WL 4080055, at *10.
[5] *Id.*, at *24.

As MPEP § 2106 indicates, "[c]omputer programs are often recited as part of a claim. Office personnel should determine whether the computer program is being claimed as part of an otherwise statutory manufacture or machine. In such a case, the claim remains statutory irrespective of the fact that a computer program is included in the claim. The same result occurs when a computer program is used in a computerized process where the computer executes the instructions set forth in the computer program. Only when the claimed invention taken as a whole is directed to a mere program listing, i.e., to only its description or expression, is it descriptive material *per se* and hence nonstatutory"

Accordingly, Applicants respectfully submit that claims 35 and 48, as amended, are directed to statutory subject matter, and, as such, request withdrawal of the rejection under 35 U.S.C. § 101. Further, each of claims 36-46 and 49-55 are believed to be in condition for allowance based, in part, upon their dependency from one of independent claims 35 and 48, and such favorable action is respectfully requested.[7]

Last, independent claims 57 and 73 have been amended herein to recite, in part, "Computer storage media containing computer-executable instructions that, when executed, perform a method." Upon amendment, it is contended that claims 57 and 73 are limited to tangible embodiments. "When functional descriptive material is recorded on some computer-readable medium, it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since the use of technology permits the function of the descriptive material to be realized."[8] As such, these claims relate to media encoded with a data structure that

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[6] *See* 37 C.F.R. § 1.75(c) (2006).
[7] *See* 37 C.F.R. § 1.75(c) (2006).
[8] MPEP § 2106.01. *See*, *In re Lowry*, 32 F.3d 1579, 1583-84 (Fed. Cir. 1994) (discussing patentable weight of data structure stored on a computer readable medium that increases computer efficiency); s*ee also*, *In re Warmerdam*, 33 F.3d 1354, 1360-61 (discussing patentable weight of data structure limitations in the context of a statutory claim to a data structure stored on a computer readable medium that increases computer efficiency).

defines structural and functional interrelationships between the data structure of the computer software and hardware components. This permits the data structure's functionality to be realized. Because claims 57 and 73 are now directed to computer-executable instructions embedded on "computer-storage media" that stores a data structure, the claims constitute physical articles that fall within the statutory classes.

Rejections based on 35 U.S.C. § 103(a)

A.) Applicable Authority

The teachings or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure.[9] To establish a *prima facie* case of obviousness, all the claim limitations must be taught by the prior art.[10] When determining whether a claim limitation is taught, "All words in a claim must be considered in judging the patentability of that claim against the prior art."[11] Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner: "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references."[12]

B.) Obviousness Rejection Based upon U.S. Patent No. 6,317,719 to Schier et al. in view of U.S. Publication No. 2002/0095313 to Haq

[9] *See* MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).
[10] MPEP § 2143.03; *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974).
[11] MPEP § 2143.03; *In re Wilson*, 57 C.C.P.A. 1029, 1032 (1970).
[12] *Ex parte Clapp*, 227 USPQ 972, 972 (Bd. Pat. App. & Inter. 1985); *see also* MPEP §706.02(j) and §2142.

Claims 1-13, 15, 17-24, 26, 28-69, 71 and 73 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,317,719 to Schrier et al. (hereinafter the "Schier reference"), in view of U.S. Publication No. 2002/0095313 to Haq (hereinafter the "Haq reference"). As the Schier reference and the Haq reference, whether taken alone or in combination, fail to teach or suggest all of the limitations of the rejected claims upon being amended, Applicants respectfully consider this rejection overcome, as hereinafter set forth. Further, claims 9, 18, 47, 56, and 71 have been canceled by way of the present communication and, accordingly, the rejections of these claims have been rendered moot.

Independent claim 1 has been amended herein to recite a clarification of the process of determining a list of possible medications to which the patient may be subjected to during a his/her medical procedure(s). In particular, this newly added clarification involves the following steps: "receiving a selection of the person [patient] from a list of patients displayed at a user interface window," where "the list of patients is extracted from patient-procedure entries stored in a unified healthcare network," and where "the patient-procedure entries associate the person with a medical procedure;" "utilizing the medical procedure associated with the selected person to interact with one or more pre-built medication-procedure tables;" and, based on the interaction, "accessing a list of possible medications, and dosages thereof, that are to be administered to the person for the medical procedure." In this way, a medical procedure is initially entered to find a list of patients slated for that medical procedure, where the list of patients is displayed to a clinician on a UI. Next the clinician can select a subject patient from the list of patients on the UI, and the medications and dosages of the subject patient will be gathered upon the selection.

The Office indicates that neither the primary reference, Schier, nor the Haq reference explicitly discloses the feature of "selecting the person from a list of persons scheduled

for a medical procedure."[13] The Office utilizes U.S. Patent No. 5,758,095 to Albaum et al. (hereinafter the "Albaum reference") to support these two references above. However, the Albaum reference does not explicitly describe or inherently consider a control server configured to (a) extract a list of patients from patient-procedure entries stored in a unified healthcare network, where the patient-procedure entries associate the person with a medical procedure, and to (b) receive a selection of the person (patient) from a list of patients displayed at a user interface window. Instead, the Albaum reference describes displaying a list 36 (see patient screen 34 of FIG. 3) that is a compilation of the physician's patients.[14] That is, the list in the Albaum reference is sorted by an assigned physician, while the "list of patients" of amended claim 1 is recited as being extracted based on "patient-procedure entries" such that each of the patients on the list share a common medical procedure. Accordingly, the Albaum reference fails to cure the above-stated deficiencies of the Schier and Haq references because none of the cited references teaches the steps (a) and (b) above.

As the Schier, the Haq, and the Albaum references, whether taken alone or in combination, fail to teach or suggest all of the limitations of the rejected claims, Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of independent claim 1, as amended, be withdrawn. Each of claims 2-8, 10-13, and 15 depend, either directly or indirectly, from independent claim 1. As such, these dependent claims are believed to be in condition for allowance at least by virtue of their dependency.[15] Consequently, allowance of each of claims 1-8, 10-13, and 15 is respectfully requested.

Continuing from the method steps discussed above, amended independent claim recites "*utilizing the medical procedure* associated with the selected person to *interact with one*

[13] Office Action at pg. 22, ll. 14-19.
[14] *See Albaum reference* at col. 7, ll. 25-65.

or more pre-built medication-procedure tables" and, based on the interaction, "*accessing a list of possible medications, and dosages thereof, that are to be administered to the person for the medical procedure*" (emphasis added). In this way, the "medical procedure" scheduled for the person is used to generate a list of all possible medications (primary and alternatives) and dosages of the medications that may be administered to the person in the context of the medical procedure.

The Office indicates that the primary reference, Schier, describes accessing a list of possible medications that may be administered prior to or during a medical procedure.[16] However, the Schier reference does not describe either (a) utilizing the medical procedure associated with the selected person to interact with a pre-built medication-procedure table, or (b) accessing a list of possible medications, and dosages thereof, that are to be administered based on the interaction (medical procedure). Instead, the Schier reference describes a process of entering a drug to generate a list of other drugs and a list of therapeutic categories.[17] Also, the Schier reference indicates that the list of other drugs can be refined by selecting one of the therapeutic categories such that the "list are only those drugs in the selected category."[18] As such, the Schier reference does not provide all possible medications and dosages for a medical procedure, but lists only drugs (subset of the claimed "medications") that are within a generalized therapeutic category (distinct from the claimed "medical procedure"). The Hag reference is not cited for curing this deficiency of the Schier reference. Accordingly, for at least this reason, amended independent claim 1, and the claims that dependent therefrom, are considered to be in condition for allowance.

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[15] *See* 37 C.F.R. § 1.75(c) (2006).
[16] Office Action at pg. 4, ll. 17-21.
[17] *See Schier reference* at col. 5, ll. 53-67.
[18] *Id.*

Further, independent claim 1 is amended to expand upon the process of "outputting a response relating to each match." Accordingly, the process is expanded to recite that "the response indicates a specific medication involved in the match, a category of the specific medication, a type of match, and a severity of an associated atypical clinical event," and that "the type of match is comprises at least one of drug-drug, drug-allergy, or drug-food." In this way, a very specific response with very particular information (i.e., matching specific medication, type of match, and severity of atypical clinical event) is presented to a clinician upon performing the claimed process. Further, the "type of match" is selected from a list of "drug-drug, drug-allergy, or drug-food."

The Office indicates that the Schier reference discloses selecting an atypical event from a list of interactions, and further indicates that the Haq reference discloses a severity of an atypical clinical event.[19] However, neither the Schier reference nor the Haq reference, as cited describes presenting (a) a type of match as being one of drug-drug, drug-allergy, or drug-food, or (b) category of a medication specified by the match. Instead, the Schier reference simply indicates that patient may be allergic to a drug.[20] This indication does not teach selection of a "type of match" from a discrete list of three choices, or a category of medication. Further, the Hag reference generally describes color-coded alarms to indicate severity.[21] This description does not teach selection of a "type of match" from a discrete list of three choices, or a category of medication. Accordingly, for at least this reason, amended independent claim 1, and the claims that dependent therefrom, are considered to be in condition for allowance.

Independent claims 17, 29, 35, 48, 57, and 73 are amended herein to recite a description of comparing a medication list against both an electronic medical record (EMR), and

[19] Office Action at pg. 9, ll. 1-20.
[20] *See Schier reference* at col. 12, ll. 45-48.

information of the EMR passed through an association table. First, the process of comparing the medication list against the EMR includes the following steps: (a) comparing "the medication list to information in the person's electronic medical record (EMR)," and determining whether "at least one match exists between any of the medications included in the list and the EMR information," where "the match indicates the potential of *drug-allergy reactions* occurring upon the associated medication being administered to the person" (emphasis added).

Second, the process of comparing the medication list against the EMR includes the following steps: (a) comparing "the medication list to the information in the person's electronic medical record (EMR) *upon being passed through an association table*," where "the association table includes information regarding adverse affects caused by medications interacting with each other and caused by a medication and a food interacting with each other;" and (b) determining whether "at least one *match exists between any of the medications included in the list and the EMR information passed through the association table*," where "*the match indicates the potential of drug-drug or food-drug reactions* occurring upon the associated medication being administered to the person" (emphasis added). In this way, "drug-allergy reactions" of a patient to a medication are identified upon comparing the medication list to information in the patient's EMR, while "drug-drug or food-drug reactions" of a patient to a medication are identified upon comparing the medication list to the EMR information passed through the association table.

The Office indicates that the Haq reference describes a comparison of drugs the patient is taking with a list of the foods the patient eats, while does not cite to the primary reference Schier for teaching such features.[22] However, the Haq reference does not describe (a)

[21] *See Haq reference* at ¶ [0112].
[22] Office Action at pg.18, ll. 4-16.

comparing the medication list to information in the patient's EMR to identify "drug-allergy reactions", but (b) comparing the medication list to the EMR information passed through the "association table" to identify "drug-drug or food-drug reactions." Instead, the Haq reference does not mention an "association table" as claimed, but generally describes accessing a drug interaction database upon entering the drugs prescribed for the patient[23] and accessing a drug/food interaction database upon entering food consumed by the patient and the drugs the patient is taking.[24] As such this disclosure of Haq does not explicitly describe or inherently consider the newly claimed features of steps (a) and (b) discussed immediately above. Further, the steps (a) and (b) provide a distinct advantage over the disclosure of a Haq and Schier: the possible medications associated with a procedure can be automatically and efficiently checked against the patient's current drug intake and food consumption (using the proper tables) and checked against the patient's allergies by accessing the EMR.

As the Schier and the Haq references, whether taken alone or in combination, fail to teach or suggest all of the limitations of the rejected claims, Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of independent claims 17, 29, 35, 48, 57, and 73, as amended, be withdrawn. Each of claims 19-24, 26, 28, 30-34, 36-46, 49-55, and 58-69 depend, either directly or indirectly, from one of independent claims 17, 29, 35, 48, and 57, respectively. As such, these dependent claims are believed to be in condition for allowance at least by virtue of their dependency.[25] Consequently, allowance of each of claims 17, 19-24, 26, 28-46, 48-55, 57-69, 71 and 73 is respectfully requested.

C.) Obviousness Rejection Based upon the Schier reference in view of the Haq and the Albaum references

[23] *See Haq reference* at ¶ [0096].

Claims 14, 16, 25, 27, 70 and 72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Schrier reference (U.S. Patent No. 6,317,719) in view of the Haq reference (U.S. Publication No. 2002/0095313), and in further view of the Albaum reference (U.S. Patent No. 5,758,095). As discussed above, independent claims 1 (from which claims 16 and 16 depend), 17 (from which claims 25 and 27 depend), and 57 (from which claim 70 depends) are amended to overcome the rejections under Schier and Hag. As cited, the Albaum reference fails to cure the above-mentioned deficiencies of the combination of Schier and Haq. Accordingly, claims 14, 16, 25, 27, and 70 are believed to be in condition for allowance for at least this reason. Further, claim 72 has been canceled by way of the present communication and, accordingly, the rejection of this claim has been rendered moot.

[24] *Id.* at ¶ [0100].
[25] *See* 37 C.F.R. § 1.75(c) (2006).

CONCLUSION

For at least the reasons stated above, claims 1-8, 10-17, 19-46, 48-55, 57-70, and 73 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned—by telephone at 816.559.2136 or via email at btabor@shb.com (such communication via email is herein expressly granted)—to resolve the same prior to issuing a subsequent action.

A Two-Month Extension of Time Fee is submitted herewith. It is believed that no additional fee is due in conjunction with the present communication. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.110414.

Respectfully submitted,

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